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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,545	08/21/2003	Douglas S. Hine	P-11138.00	9714

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EXAMINER	
ALTER, ALYSSA MARGO	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,545	HINE ET AL.	
	Examiner	Art Unit	
	ALYSSA M. ALTER	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 11-14* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claim 14 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions I (claims 1-6 and 11-13) and II (claim 14) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs. Invention II differs from Invention I, because Invention II requires the employment of a connector block positioned along the inner surface of the connector bore.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 14 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicant's arguments filed January 9, 2008 have been fully considered but they are not persuasive. The Applicant argues that Pohndorf et al. does not disclose all the elements of claim 1. However, the examiner respectfully disagrees. Pohndorf et al. discloses two adapters, as seen in figures 6 and 7, sized to engage in the connection bore of the IMD. Both of the adapters have internal surfaces which form lumens sized to receive a single lead. Specifically "the second adapter ...forming a second lumen to receive the single lead". Therefore, Pohndorf et al. meets the limitation by disclosing two

adapters with lumens sized or formed to receive the single lead. Thus, the claims stand rejected under Pohndorf et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

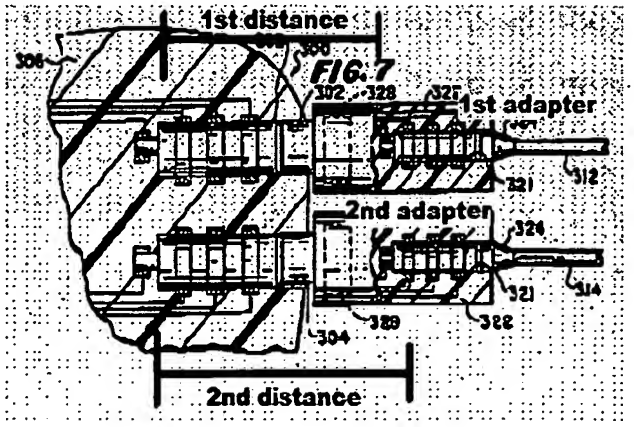
1. Claims 1, 3-4, 6 and 11-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses a pacemaker with a connector bore for electrically and mechanically connecting the implantable medical device (IMD) with two adapters and multi-electrode leads as displayed in figures 6 and 7. The adapters upsize the leads prior to the insertion into the connector bore within the IMD. The array of lead connector elements are displayed in figure 2 as "sleeves 151 and 152 (in contact with rings 141 and 142) (col. 7, lines 63-64)". The sleeves are connected to electrodes, with a conductor for each electrode. The two adaptors, which the examiner considers the to be a plurality of adaptors, have an inner lumen for engaging the sleeves of the lead with rings to create an electrical and mechanical connection. In addition, the adaptors have an external surface used for engagement with the electrical bore. This engagement surface has two contact zones, the pin as the first zone and sleeves of the lead as the second zone, which connects within the IMD with the socket and rings, respectively.

Since the lead connectors are located circumferentially around the lead, the examiner considers the connectors to be connector rings. In addition, a connector ring is located adjacent to the sealing ring and distal to the remainder of the array of lead connectors. Therefore, since the ring conductor makes contact with the bore of the IMD by means of the adaptor, the connector ring is located distal to the array of lead connector elements and electrically connected to the IMD bore.

Within the adaptor-lead connector, there are two sealing rings. One sealing ring, as previously mentioned, is located distal to the array of connector elements located on the lead. The other sealing ring is located on the adaptor located proximal to the array of connector elements.

Outer surface of a male connector piece closely matched the inner surface of a female connector piece the connection assembly is dimensioned to be press fit. Therefore, since the sleeves or array of lead connector elements on the cylindrical male piece closely match the rings or contact elements located within the adaptor on a cylindrical female piece, the connection assembly is press fit.

As to claims 1 and 11, the examiner has included a replication of figure 7 to display the first and second distances. The examiner considers the first distance is to the first contact zone and the second distance is to the second contact zone. Therefore the first distance is not equal to the second distance.



Furthermore, as to claim 1, Pohndorf et al. discloses two adapters, as seen in figures 6 and 7, sized to engage in the connection bore of the IMD. Both of the adapters have internal surfaces which form lumens sized to receive a single lead. Specifically "the second adapter ...forming a second lumen to receive the single lead". Therefore, Pohndorf et al. meets the limitation by disclosing two adapters with lumens sized or formed to receive the single lead

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 2 stands rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses the claimed invention except for the external surface conforming to industry standard. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the external surfaces as taught by Pohndorf et al. with external surfaces conforming to industry

standard since it was known in the art to construct medical devices to an industry standard to ensure quality and uniformity.

2. Claim 5 stands rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934) in view of Peers-Trevarton (US 4,469,104). Holleman et al. discloses the claimed invention except for the protrusions for each contact element within the array of lead contact elements. Peers-Trevarton teaches that it is known to utilize protrusions and depressions to securely mechanically and electrically engage the lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical connections of the lead as taught by Pohndorf et al. with the electrical and mechanical connections as taught by Peers-Trevarton since such a modification would be a substitution of known functional equivalents by substituting electrical connectors to electrically engage the lead.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762